UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,671	08/04/2005	Mauro Napoletano	265084US0PCT	8632

22850 7590 04/24/2008

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
PESELEV, ELLI	
ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
04/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/522,671	NAPOLETANO ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,10-20,30 and 32* is/are rejected.

7)☒ Claim(s) *4, 5, 8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 12, 2008 has been entered.

The disclosure is objected to because of the following informalities: the specification on page 1 fails to state that this application is a 371 of PCT/EP03/08448 filed 07/29/2003.

Appropriate correction is required.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating an inflammatory disease, does not reasonably provide enablement for prophylaxis of an inflammatory disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

Claim 30 encompasses a method for prophylaxis an inflammatory disease. The term "prophylaxis" reads on treating healthy patients and preventing said patients from ever having an inflammatory disease.

(B) The state of the prior art.

Prevention of inflammatory diseases is not known in the art using erythromycin derivatives.

(C) The amount of direction provided by the inventor.

The inventor has not provided any direction on how to use the claimed compounds for the purpose of prophylaxis i.e. on how to select patients in need of prophylaxis and whether prophylaxis is effective for a period of days, months, years or whether permanent prophylaxis is achieved.

(D) The existence of working examples.

The working example 77 is directed to the treatment of acute contact dermatitis and pulmonary inflammation. No examples have been provided showing the effectiveness of the claimed method in prophylaxis of inflammatory diseases.

(E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Since there is no way to predict the effectiveness of the claimed method in prophylaxis of pulmonary diseases, it would take an undue amount of experimentation to determine said effectiveness.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of pulmonary inflammation, does

not reasonably provide enablement for treating a respiratory disease in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

Claim 30 reds on the treatment of any respiratory disease, including infection, inflammation and cancer.

(B) The state of the prior art.

Erythromycin derivatives are known to possess antibiotic and anti-inflammatory activity.

(C) The amount of direction provided by the inventor.

The inventor has failed to describe for which respiratory diseases, other than pulmonary inflammation, the claimed method is useful.

(D) The existence of working examples.

The only working example set forth in the specification is directed to the treatment of pulmonary inflammation.

(E) The quantity of experimentation needed to make and/or use the invention based on the content of the disclosure.

Because there is no way to predict for the treatment of which other respiratory diseases, besides pulmonary inflammation, the claimed method would be useful, it would take an undue amount of experimentation to test the claimed method on many types of unrelated respiratory diseases.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "a composition according to Claim 30" renders claim 32 indefinite since claim 30 is a compound claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6, 7, 10-16, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnet et al (U.S. Patent No. 5,969,161).

Bonnet et al disclose the a closely analogous erythromycin derivative wherein R is hydrogen or methyl, R1 is a dimethylamino group, R2 is hydrogen and R3 and R4 for an oxime group (columns 3 and 4). The only difference between the claimed compound and the prior art compound is at the 3'-position, i.e. the reference compound contains a dimethylamino group at the 3'-position while the claimed compound contains a methyl ethyl amino group at the 3'-position. However, since methyl ethyl group is a next higher homologue of a dimethylamino group, it would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made to substitute a methyl ethyl amino group for the dimethylamino group at the 3'-position on the reference's compound because such a person would have expected the resulting compound to possess similar activity. Further, since erythromycin is known for the treatment of respiratory conditions, as set forth on page 27 of the specification, it would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made to use the claimed compounds for the treatment of respiratory conditions.

Applicant's arguments filed February 12, 2008 have been fully considered but they are not persuasive.

Applicant contends that Bonnet et al do not disclose or suggest the claimed compound because of the proviso that R1 is not a dimethylamino group when R5 is a hydrogen , a linear or branched C10C5 alkyl or unsubstituted benzyl. This argument has not been found persuasive because the present claims still encompass compound having a methyl ethyl amino group at the 3'-position. Such a compound is considered prima facie obvious over the disclosure by Bonnet et al for the reasons as set forth above.

Claims 1-3, 6-7, 10-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundy et al (U.S. Patent No. 6,043,226).

Lundy et al disclose closely analogous erythromycin derivatives wherein R is a hydrogen atom or a methyl group, R1 is dimethylamino, R2 is hydrogen, R3 is hydroxyl and R4 is hydrogen (column 10). The only difference between the claimed compounds and the prior art's compound is at the 3'-position i.e. the reference's compounds possess a dimethylamino group at the 3'-position while the claimed compounds possess a methyl ethyl amino group at the 3'-position. Since methyl ethyl amino group is a next higher homologue of dimethylamino group, the claimed compounds are prima facie over Lundy et al because said compounds would be expected to possess similar activities.

Applicant's arguments filed February 12, 2008 have been fully considered but they are not persuasive.

Applicant contends that the proviso "R1 is not a dimethylamino group when R3 is hydroxy, and both R2 and R4 are hydrogens" excludes compounds disclosed by Lundy

et al. This argument has not been found persuasive because the claimed compounds read on a next higher homologue of a dimethylamino group. Applicant has not presented any evidence that such a minor change would significantly effect the activity of the claimed compounds as compared to the activity of the reference's compound.

Claims 20 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ku et al (U.S. Patent No. 5,892,008).

Ku et al disclose closely analogous erythromycin derivatives wherein R is methyl, R1 is dimethylamino group, R2 is hydrogen and one of R3 and R4 is hydrogen and the other is hydroxy (column 6, compound (6)) but do not disclose erythromycin derivatives wherein R1 is a methyl ethyl amino group. However, since methyl ethyl amino group is a next higher homologue of a dimethylamino group, the claimed compounds are still deemed to be prima facie obvious over the reference's compounds for the same reasons as set forth above.

Applicant's arguments filed February 12, 2008 have been fully considered but they are not persuasive.

Applicant contends that Ku fails to disclose the claimed compound because claim 20 recites that "R1 is not an N,N-dimethyl amino group". This argument has not been found persuasive because the claimed compounds still encompass a methyl ethyl amino group. Since methyl ethyl amino group is a next higher homologue of a dimethylamino group, the claimed compounds are still deemed prima facie obvious over Ku et al for the same reasons as set forth above.

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnet et al (U.S. Patent No. 5,696,161) or Lundy et al (U.S. Patent No. 6,043,226) in combination with Agouridas et al (U.S. Patent No. 6,096,714).

Each of Bonnet et al and Lundy et al discloses closely analogous erythromycin derivatives but does not disclose a process for preparing the same by removing a cladinose moiety by acid hydrolysis. However, since removal of a cladinose group by acid hydrolysis from an erythromycin derivative was well known in the art at the time the claimed invention was made as disclosed by Agouridas et al (column 4, lines 47-50), it would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made to prepare derivatives disclosed by Bonnet et al or Lundy et al using the conventional method disclosed by Agouridas et al.

Applicant's arguments filed February 12, 2008 have been fully considered but they are not persuasive.

As set forth above, the compounds prepared by the process claims 17-19 are deemed prima facie obvious over the compounds disclosed by Bonnet et al or Lundy et al. Therefore, the conventional process for preparing said compounds is also deemed to be prima facie obvious in view of the teachings by Agouridas et al.

Claims 4, 5, 8, 9 and 21-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

/Elli Peselev/

Primary Examiner, Art Unit 1623